

K944459

APR 17 1996

Attachment #5

Summary of Safety and Effectiveness

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Summary of Safety and Effectiveness

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Boehringer Mannheim Corporation
 9115 Hague Road
 Indianapolis, Indiana 46250
 Contact Person: Michael Flis
 October 23, 1995
 2. Panel = Clinical Chemistry (75)
 Classification No = CGA
 Classification Name = Glucose Oxidase, Glucose
 Regulation No = 21 CFR 862.1345
 Classification = II
 3. We claim equivalence to Boehringer Mannheim Corporation's Accu-Chek® Easy™ System.
 4. The Instant™ Test Strip, when used as directed with either the Accu-Chek® InstantPlus or Instant DM Monitor, will accurately measure the blood glucose value. The strip changes color as it reacts to glucose in a drop of blood, and the monitor measures this color change. The monitor displays the blood glucose result.
 5. Intended Use: For use by professionals and people with diabetes for the quantitative determination of glucose in whole blood.
 6. As noted above in section 3, we claim equivalence to Boehringer Mannheim Corporation's Accu-Chek® Easy™ System.
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SUMMARY OF SAFETY AND EFFECTIVENESS

ACCUTREND® GLUCOSE TEST

The Accutrend® Glucose Test is substantially equivalent to our Accu-Chek Easy Self Blood Glucose Monitoring System. Both systems are used to measure glucose in whole blood. The procedure for both tests entails applying a capillary blood sample to a dry chemistry test strip. Both test system utilize non-wipe technologies. The glucose oxidase reaction is measured in both tests. Both test systems have lot-specific coding for each lot of test strips. Finally, both the Accutrend GC and Accu-Chek Easy systems are blood glucose monitoring devices which have been cleared specially for home use.

Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46256

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